

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA ex rel.,	§	
TIFFANY MONTCRIEFF, et al.,	§	
	§	
Relators, Plaintiff,	§	
	§	
v.	§	Civil Action No. 5:17-CV-00317-XR
	§	
PERIPHERAL VASCULAR	§	
ASSOCIATES, P.A.,	§	
	§	
Defendant.	§	

DEFENDANT’S REPLY IN SUPPORT OF ITS
MOTION TO EXCLUDE TESTIMONY OF JAMES E. ALEXANDER M.D.

Defendants file this Reply in support of their Motion to Exclude the Testimony of James E. Alexander, M.D. (the “Motion”) [Dkt. No. 82].

I. INTRODUCTION

Relators attempt to obscure Dr. James A. Alexander’s lack of specialized knowledge behind a long career devoid of relevant experience with the hope of propping him up to serve as a mouthpiece for Relators’ theories. Left with little support for Dr. Alexander’s designation as an expert, Relators use their Opposition to once again change the theory of their case, which has become an exercise in shape shifting, to lodge new allegations regarding upcoding and recklessness. Instead of Dr. Alexander’s testimony supporting the theory of their case, they belatedly attempt to bend the theory of their case to fit Dr. Alexander’s testimony and shoehorn his ill-informed opinions.¹ “A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.” *Wilson*

¹ Given the page limits for reply briefs, Defendants do not attempt to rebut every argument in Relators’ Opposition to the Motion (“Opposition”) [Dkt. No. 85], in particular Relators’ newly formed allegations being inappropriately raised for the first time in an opposition motion pertaining to their unqualified expert witness. Capitalized terms in this Reply have the same meaning as in the Motion.

v. Woods, 163 F.3d 935, 937 (5th Cir. 1999). His Reports and testimony are clearly improper under Federal Rule of Evidence (“FRE”) 702 and should be excluded as he does not provide specialized or technical expertise and is likely to confuse and mislead a jury. Specifically:

- Dr. Alexander has never practiced vascular medicine, has no specialized knowledge or training in vascular medicine, and hasn’t been a practicing physician since 1994, last seeing patients on a volunteer basis in 2000;
- Dr. Alexander attempts to testify regarding billing and coding requirements despite having no specialized knowledge in billing and coding;
- Relators inflate Dr. Alexander’s limited years as one of several medical directors for Trailblazer, even though his role relied on other employees on other teams for coding and billing knowledge;
- Dr. Alexander’s testimony evidenced a rudimentary appreciation of Medicare requirements at the heart of this misbegotten case, at times displaying confusion, and at other times making demonstrably false statements;
- Relators understandably don’t attempt to support Dr. Alexander’s improper and unsupportable parsing of medical necessity into regulatory and clinical medical necessity, which in addition to being baseless, will mislead and confuse a jury;
- Dr. Alexander’s parroting of Realtors’ allegations demonstrates a lack of independent knowledge or expertise;
- Dr. Alexander agrees with PVA that there is no statutory or regulatory requirement for a stand-alone written report as a Medicare condition of payment and had to disavow his only example of PVA’s improper conduct when presented with medical records for the one patient he identified in support of the baseless representation in his Reports;
- The majority of Dr. Alexander’s expert reports² contain speculative opinions that will not benefit the trier of fact and are likely to confuse and mislead the jury, and prejudice PVA.

Relators remain stubbornly befuddled about what constitutes binding requirements on Medicare providers and misconstrue foundational concepts of administrative law. For instance, they now unimaginatively attempt to bootstrap the American Medical Association’s Current Procedural Terminology (“CPT”) guide book into a Medicare condition of payment. Relators’ only support is to cite to the adoption of CPT codes as a standard medical data code set under Medicare.³ Critically, they are missing any requirement linking this adoption to an obligation of a Medicare Part B provider like PVA to follow other *guidance* from a private, non-governmental

² Dr. Alexander’s original expert report was signed on March 26, 2020, and a supplemental expert report was served on July 8, 2020. Dr. Alexander’s supplemental expert report is the same as his original expert report with additional information and is attached hereto as Exhibit B (“Supp. Report”).

³ See generally 45 C.F.R. §162.1002.

entity. Even if Relators were able to tie AMA guidelines to a Medicare regulation, under the Supreme Court’s ruling in *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1813, (2019), sub-regulatory guidance, or Medicare interpretive rules, cannot establish or change a substantive legal standard without first going through notice and comment rulemaking. To be clear, AMA guidelines do not even rise to the level of sub-regulatory guidance, yet it remains Relators’ only support for their contention regarding a stand-alone written report.

II. REPLY POINTS

A. **Relators’ generous characterization of Dr. Alexander’s qualifications does not overcome his likelihood of confusing and misleading the jury.**

Despite attending Vanderbilt University, Dr. Alexander is simply not qualified to opine on vascular imaging/surgery or Medicare billing requirements. His billing and coding opinions are unreliable speculation that do not aid the trier of fact. Relators engage in significant puffery in an attempt to cloud clear testimony to the contrary. For instance, Relators embellish Dr. Alexander’s work history by claiming that he “served as *the* head Medical Director for Medicare in the State of Texas.”⁴ Dr. Alexander testified, however, that there were six medical directors across Trailblazer’s multi-state operation, and that the individuals specializing in reviewing billing and coding for claim submission to Medicare “were on other teams.”⁵ Additionally, his experience bears no relevance to how the current Medicare Administrative Contractor—Novitas Solutions, Inc. since 2012—would make decisions, or on what the Government—here, the Centers for Medicare & Medicaid Service (“CMS”)—requires.

PVA is a single specialty vascular practice, primarily treating patients referred by general practitioners, such as Dr. Alexander used to be. Dr. Alexander’s background is general surgery.

⁴ Relators’ Opposition To Defendant’s Motion To Exclude Relators’ Expert Witness James Alexander, M.D., Dkt. 85, (“Opposition”) at p. 16.

⁵ Remote Oral Deposition of James E. Alexander, Jr., MD (“Tr.”), attached as Exhibit A, Tr. 32:4-35:6.

He was never a vascular surgeon, has never performed an ultrasound study, is not a specialist in the field, and has no experience with the practice tools used at PVA.⁶ In fact, Dr. Alexander ceased being an actively-practicing physician in 1994 and has not seen patients since 2000.⁷ A medical doctor who is an expert in a particular field of medicine is not an expert in all areas of medicine. *Kallassy v. Cirruss Design Corp.*, No. 3:04-CV-0727N, 2006 WL 1489248, at *7 (N.D. Tex. May 20, 2006). As part of its gatekeeping role, the Court must evaluate whether proffered expert testimony from a clinical physician is “soundly grounded in the principles and methodology of [her] field of clinical medicine.” *Anderson v. Bristol Myers Squibb Co.*, No. H-95-0003, 1998 WL 35178199, at *6 (S.D. Tex. Apr. 20, 1998); *see also Washington v. United States*, No. 99-50143, 1999 WL 1093659, at *1 (5th Cir. Oct. 27, 1999) (finding no error in district court’s exclusion of expert testimony from physician who was not of “same school of practice” as physicians whose care was at issue).

Moreover, the crux of Relators’ claims rest on their mistaken allegations related to PVA’s use of MedStreaming, a picture archiving and communication system. Yet, they continue show a fundamental misunderstanding of how PVA uses MedStreaming. Without citation, they offer that “there are hundreds of PACS systems available for radiology use” and “all have the same basic functionality, and must meet the basic standards for electronic medical record systems.”⁸ Similarly, Dr. Alexander also incorrectly referred to MedStreaming as an electronic medical records system when admitting he has never used MedStreaming.⁹ PVA does not use MedStreaming as an electronic medical records system. PVA uses MedStreaming to store its ultrasound images and to create reports for its IAC accreditation.¹⁰ PVA also uses MedStreaming

⁶ Ex. A, Tr. 55:9-11.

⁷ Ex. A, Tr. 25:19-26:6.

⁸ Opposition at p. 17.

⁹ Ex. A, Tr. 101:11-20.

¹⁰ Remote Oral Deposition of Barbara Burrow (“Tr.”), attached as Exhibit C, Tr. 72:25-73:6.

to assist referring physicians that don't have a background in vascular medicine, like Dr. Alexander, to "send the reports in the pretty format, in an easy-to-understand format, to referring physicians so they can use it to show—to talk to their patients."¹¹ Dr. Alexander has no idea how the practice of vascular medicine works, and he should not be allowed to tell a jury how it should work.

Dr. Alexander's Reports and testimony should be excluded because his testimony reflects his lack of knowledge regarding Medicare requirements that specifically undermines his reliability and demonstrates the likelihood that his testimony would confuse and prejudice a jury. Critically, He could not answer whether a guidance document from a Medicare contractor is binding on CMS, stating that he did not know "how that would be considered administratively within DHHS."¹² That testimony underscores why Dr. Alexander should be excluded from this case—he cannot say how CMS would view a guidance document. But that is precisely the point on which Relators offer his opinions. Additional examples of Dr. Alexander's lack of knowledge regarding Medicare include:

- He was only able to vaguely testify to what he considered "requirements for payment" and that "[a]lthough, 'conditions for payment' is a term that I have heard, but I don't think it's any different than requirements for payment."¹³
- Dr. Alexander repeatedly references a non-existent requirement for a stand-alone written report in order for a physician to submit a claim for the provision of the professional component of a vascular study, yet admitted at his deposition that he could not identify a single federal statute or regulation, like an actual condition of payment, requiring a stand-alone written report.¹⁴
- He falsely opined there is a Local Coverage Determination Requirement for a stand-alone written report and was left with no choice but to admit during his deposition that there is, in fact, no such requirement.¹⁵

¹¹ *Id.*

¹² Ex. A, Tr. 35:16-37:20.

¹³ Ex. A, Tr. 46:6-17.

¹⁴ Ex. B, Supp. Report at p. 10; 15; 16; 20; and 21; Ex. A, Tr. 146:24-150:22.

¹⁵ Ex. A, Tr. 171:7 – 178:16. (Q: So you do not – a laboratory does not have to be accredited in order to bill Medicare for vascular studies. Correct? A: That's interesting. Yeah. Okay." Tr. 177:12-15).

Relators cite to *United States v. Galatis*, 849 F.3d 455 (1st Cir. 2017), to support their argument that testimony referencing legal requirements is allowed as long as it helps the jury understand the expert's analysis and conclusions.¹⁶ Relators argue that the *Galatis* court's allowance of a Medicare fraud investigator to testify about the structure of the Social Security Act, Medicare regulations, and Policy Manual supports the admissibility of Dr. Alexander's opinions.¹⁷ But the *Galatis* court made clear that the expert was qualified by experience to "introduce to the jury the regulatory regime that is out there, but that she could not opine about [the relevant] provisions or be someone who comes in and says when people do this [then it] is fraud." *United States v. Galatis*, 849 F.3d 455, 462 (1st Cir. 2017) (internal quotations omitted). The court further noted that the expert "never purported to offer an interpretive gloss on the legal meaning of the regulations" and "never applied the regulations to the facts of the case or suggested that any actions by [the defendant] had violated the law." *Id.* Dr. Alexander does not offer opinions about the regulatory scheme in general. In fact, he disclaims to know how CMS would view guidance documents while at the same time crowning non-governmental guidance as Medicare *requirements*. Relators highlight that point by arguing that Dr. Alexander properly relies on "industry publications" to reach a conclusion that some act is prohibited by Medicare.¹⁸ Those "industry publications" are not Medicare regulations, guidance, or anything issued by the Government. Two of the publications are published by a urology group, one is of unknown origin, and the rest are accreditation guidelines from the American College of Radiology, by which PVA is not accredited.¹⁹ Relators want this Court to allow Dr. Alexander to offer testimony of the exact type explicitly not allowed in *Galatis*, so he can testify, directly or indirectly, that PVA violated

¹⁶ Opposition at 20.

¹⁷ Opposition at 20.

¹⁸ Opposition at 10.

¹⁹ Opposition at 10 (citing Alexander Supp. Report, Exs. 23-29).

his version of the law. In no uncertain terms, Dr. Alexander provided numerous instances of inaccurate and misleading opinions that will not assist the trier of fact and will instead mislead and confuse the jury. Dr. Alexander does not possess the specialized knowledge or expertise required under section 702, and the Court should exclude his Reports and testimony. Relators' characterization of Dr. Alexander's testimony as being based on reliable principles does not make them proper.

Relators confusingly seek to bolster Dr. Alexander's opinions by citing to PVA's requirements associated with their accreditation by the Intersocietal Accreditation Commission ("IAC").²⁰ This is another red herring. While certain PVA laboratories are accredited by the IAC, and have been uninterrupted since 2013, they are not required to be accredited. Relators are attempting to bootstrap compliance with accreditation standards in relation to "one option"²¹ of satisfying one component of a nonbinding Local Coverage Determination by Novitas, in order to support their theory. That nonbinding Local Coverage Determination provides options for who can perform vascular studies, and it is undisputed that PVA satisfies more than one of the options and is not required to be accredited. The Court should reject this testimony by Dr. Alexander.

Further, Relators ignore the problematic portions of Dr. Alexander's opinions that render them improper. Relators argue that Dr. Alexander's review of "PVA's patient records and information was more than sufficient to familiarize himself with PVA's practices and procedures".²² His deposition testimony makes clear this is an inaccurate representation. Despite claiming in his Report that a PVA patient was a "good example" of an improper Medicare claim submitted by PVA, Dr. Alexander had no choice but to acknowledge that patient's claims looked

²⁰ Opposition at 17.

²¹ Opposition at 20.

²² Opposition at 20.

proper after reviewing additional medical records not in his file.²³ Dr. Alexander's reliance on incomplete medical records in support of his opinions render them inaccurate and likely to mislead a jury.

Further, Dr. Alexander's opinions are speculative and will mislead the jury. Relators argue he should be able to testify regarding their allegation of "rubber stamping." Yet, Dr. Alexander has no independent or specialized knowledge to assist the trier of fact. Dr. Alexander has no familiarity with the MedStreaming system specifically, or vascular practice generally, that would allow him to opine about how images are reviewed, should be reviewed, or the significance of a date stamp in MedStreaming. His opinion is clearly conjecture when he states that "the physician on the bill to Medicare may not match the physician who ultimately read the report" (emphasis added).²⁴ Dr. Alexander has no evidence to support this opinion. A district court should exclude expert testimony that relies on pure speculation. *See Guillory v. Domtar Indus., Inc.*, 95 F.3d 1320, 1330–31 (5th Cir. 1996). Dr. Alexander meekly offered "I don't know" when asked whether he had seen evidence of this accusation and then attempted to state that it was "very suspicious."²⁵ "Very suspicious" is far from an expert opinion. However, this is understandable since Dr. Alexander is merely repeating statements from Relators' data analyst without providing an opinion based on individual or specialized knowledge. "If the foundational data underlying opinion testimony are unreliable, an expert will not be permitted to base an opinion on that data because any opinion drawn from that data is likewise unreliable." *Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706, 714 (Tex. 1997), cert. denied, 523 U.S. 1119, 118 S.Ct. 1799 (1998). In short,

²³ Ex. A, Tr. 83:2-97:19; Ex. B, Supp. Report at p. 13. In his supplemental report, Dr. Alexander cites to Dr. Nye's analysis that "from 2015 to 2019, there were 40,102 charges by PVA for imaging studies that were submitted prior to the final interpretation and report (PC) being performed." Report at 14. Dr. Alexander states in his report that "for many of PVA's patients, there is no patient visit" yet testified that he has not looked records to determine how many patients did not have a patient visit. Id.; Tr. 104:10-19. Instead, he says that "I think Dr. Nye has looked at it." Tr. 104:10-19.

²⁴ Ex. B, Supp. Report at p. 16.

²⁵ Ex. A, Tr. 136:19-137:12; 138:22-23.

Relators cannot simply cloak Dr. Alexander's opinions as proper by ignoring the inflammatory and otherwise problematic language Alexander uses to assert his opinions. Simply put, cross-examination is not an adequate remedy because the risk is too high for Dr. Alexander's misplaced and demonstrably false testimony to improperly prejudice the trier of fact.

Further, Relators contend Dr. Alexander's false representations and misleading testimony should be permitted to counter a defense PVA has not put forth.²⁶ Dr. Alexander has no basis for such testimony: he is not a vascular specialist, was never a vascular surgeon, hasn't treated patients in over two decades, and has no basis to opine about alleged harm to patients. In fact, when questioned about his reckless insinuation of patient harm, he immediately retreated and stated "I'm not making that allegation in any way."²⁷ Yet, in his Supplemental Report, Dr. Alexander poses the following improper and unsubstantiated rhetorical questions:

- Would the patient have had the failure of the original artery and vein surgery performed in the PVA physician had done the final physician interpretation and report on December 13, 2016 when the vascular ultrasound of the artery was done?²⁸
- Was there something that the vascular ultrasound technician missed while doing the technical procedure that a complete physician interpretation and report would have discovered on December 13, 2016?²⁹
- Would such a discovery have changed the type of artery and vein surgery that was later done and failed?³⁰

Increasing the likelihood of prejudice from Dr. Alexander's testimony is that Relators state they intend to offer his testimony to satisfy the scienter requirement of their FCA claims. Relators want Dr. Alexander to testify about what PVA knew and whether it acted intentionally or recklessly. Relators argue they should be able to present this "evidence" regarding "patient health and safety."³¹ Contrary to Relators' position, experts cannot backdoor improper testimony about a

²⁶ Opposition at p. 21.

²⁷ Ex. B, Supp. Report at 16-17; Ex. C, Tr. 58:3-6.

²⁸ Exhibit B, Supp. Report at 17.

²⁹ *Id.*

³⁰ *Id.*

³¹ Opposition at p. 17-18.

party's state of mind by offering testimony that indirectly implies such state of mind. *See Vista Hospice Care, Inc.*, 2016 WL 3449833, at *15 (holding that it is improper for experts to characterize evidence "because the trier of fact is entirely capable of determining whether or not to draw such conclusions without any technical assistance from . . . experts."). That is exactly what Dr. Alexander's rhetorical questions are designed to do. Moreover, Relators acknowledge that experts at trial will not ask questions, they will answer them. There is therefore no reason for Dr. Alexander to offer rhetorical questions about PVA's patients when it would be improper for him to answer the very questions he poses. It is also not proper for an expert to provide opinions that merely reiterate what lawyers can offer in argument. *See Salas v. Carpenter*, 980 F.2d 299, 305 (5th Cir. 1992).

B. Alexander's farcical creation of Medicare requirements are confusing and improper.

Relators inexplicably argue that Dr. Alexander's opinions regarding "reasonable and necessary" are correct and "PVA's arguments to the contrary are misleading."³² PVA's position is simple: FRE 702 does not permit experts to testify to requirements that don't exist. Theodor Herzl's famous axiom that "if you will it, it is no fairy tale"³³ does not apply when it comes to FRE 702. Dr. Alexander imaginatively testified to a non-existent requirement of "regulatory medical necessity" that will serve no purpose beyond misleading and confusing a jury.³⁴ Dr. Alexander was unsurprisingly unable to cite to a regulation that defines this concept.³⁵ Dr. Alexander so overtly misstates this Medicare "requirement" that Relators make no attempt to recast it as proper. Relators' silence all but admits that this opinion is over the line.

³² Opposition at p. 20.

³³ https://knesset.gov.il/vip/herzl/eng/Herz_Bio_eng.html

³⁴ Ex. A, Tr. at 111:9 – 112:22.

³⁵ Ex. A, Tr. at 114:21 – 126:24.

III. CONCLUSION

For these reasons, the Court should grant Defendants' Motion and exclude the testimony and opinions of Dr. Alexander.

Dated: August 18, 2020

Respectfully submitted,

By: /s/ Sean McKenna

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CERTIFICATE OF CONFERENCE

I hereby certify that on August 18, 2020, counsel for Defendant conferred with counsel for Relators regarding the contents of this motion and the relief requested herein. Relators' counsel is opposed to this motion.

/s/ Sean McKenna

Sean McKenna

CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of August, 2020, I electronically filed the foregoing instrument with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following counsel of record:

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